INVITATION TO BID NO: 11-X-2219994

STATE OF ALABAMA

DEPTARTMENT OF FINANCE
DIVISION OF PURCHASING

INVITATION TO BID

REQ. AGENCY : 011000
DEPARTMENT OF PUBLIC HEALTH
AGENCY REQ. NO. :
T-NUMBER : TA024
DATE ISSUED : 07/21/10
VENDOR NO. :
VENDOR PHONE NO. :
SNAP REQ. NO. : 1443533
BUYER NAME : BERNIE ARANT

FOR: DIAGNOSTIC EQUIP. & SUPPLIES

BUYER PHONE NO. : (334) 242-4201-
PURCHASING PHONE NO: (334) 242-7250

BID MUST BE RECEIVED BEFORE:
DATE: 08/24/10 TIME: 5:00 PM

BIDS WILL BE PUBLICLY OPENED:
DATE: 08/25/10 TIME: 10:00 AM

TO BE COMPLETED BY VENDOR

INFORMATION IN THIS SECTION SHOULD BE PROVIDED, AS APPROPRIATE. BID RESPONSE MUST BE IN INK OR TYPED WITH ORIGINAL SIGNATURE AND NOTARIZATION.

1. DELIVERY: CAN BE MADE _____ DAYS OR _____ WEEKS AFTER RECEIPT OF ORDER

2. TERMS: _____(DISCOUNTS ARE TAKEN WITHOUT REGARD TO DATE OF PAYMENT.)

3. PRICE VALID FOR ACCEPTANCE WITHIN _____ DAYS.

4. VENDOR QUOTATION REFERENCE NUMBER, IF ANY: _____
(THIS NUMBER WILL APPEAR ON THE PURCHASE ORDER.)

5. E-MAIL ADDRESS: _____

INTERNET WEBSITE: _____

6. GENERAL CONTRACTOR'S LICENSE NO: _____

TYPE OF G.C. LICENSE: _____

***** IMPORTANT NOTE: *****
BIDDERS MUST COMPLY WITH ALL "BID RESPONSE INSTRUCTIONS" ON PAGE 2, TO INCLUDE ITEM 7 - COPY REQUIREMENT.

RETURN INVITATION TO BID:

US MAIL

STATE OF ALABAMA
DEPARTMENT OF FINANCE
DIVISION OF PURCHASING
P O BOX 302620
MONTGOMERY, AL 36130-2620

COURIER

STATE OF ALABAMA
DIVISION OF PURCHASING
RSA UNION BUILDING
100 N. UNION ST., SUITE 192
MONTGOMERY, AL 36104

SIGNATURE AND NOTARIZATION REQUIRED

I HAVE READ THE ENTIRE BID AND AGREE TO FURNISH EACH ITEM OFFERED AT THE PRICE QUOTED. I HERBY AFFIRM I HAVE NOT BEEN IN ANY AGREEMENT OR COLLUSION AMONG BIDDERS IN RESTRAINT OF FREEDOM OF COMPETITION BY AGREEMENT TO BID AT A FIXED PRICE OR TO REFRAIN FROM BIDDING.

SWORN TO AND

SUBSCRIBED BEFORE ME THIS

_____ DAY OF _____

_____
NOTARY PUBLIC

TERM EXP: _____

_____
FEIN OR SSN

_____
COMPANY NAME

_____
MAIL ADDRESS

_____
CITY, STATE, ZIP

_____
PHONE INCLUDING AREA CODE

_____
AUTHORIZED SIGNATURE (INK)

_____
TYPE/PRINT AUTHORIZED NAME

_____
TITLE

_____
TOLL FREE NUMBER

_____
FAX NUMBER

STANDARD TERMS & CONDITIONS

VENDOR NAME :

VENDOR NUMBER: -

ITB NO. : 11-X-2219994 PAGE 2

INVITATION TO BID

OPEN DATE : 08/25/10 TIME: 10:00 AM

T-NUMBER : TA024

RETURN DATE: 08/24/10 TIME: 5:00 PM

AUTHORITY:
THE DEPARTMENT OF FINANCE CODE OF ADMINISTRATIVE PROCEDURE, CHAPTER 355-4-1 EFFECTIVE DECEMBER 20, 2001 IS INCORPORATED BY REFERENCE AND MADE A PART OF T HIS DOCUMENT. TO RECEIVE A COPY CALL (334)242-7250, OR OUR WEBSITE WWW.PURCHASING.ALABAMA.GOV .

INFORMATION AND ASSISTANCE TO MINORITY AND WOMEN-OWNED BUSINESSES IN ACQUIRING M/WBE CERTIFICATION MAY BE OBTAINED FROM THE OFFICE OF MINORITY BUSINESS ENTERPRISE, 1-800-447-4191.

BID (ITB) RESPONSE INSTRUCTIONS REV: 01/14/10

1. TO SUBMIT A RESPONSIVE BID, READ THESE INSTRUCTIONS, ALL TERMS, CONDITIONS AND SPECIFICATIONS.

2. BID ENVELOPES/PACKAGES/BOXES MUST BE IDENTIFIED ON FRONT, PREFERABLY LOWER LEFT CORNER AND BE VISIBLE WITH THE BID NUMBER AND OPENING DATE. EACH INDIVIDUAL BID (IDENTIFIED BY A UNIQUE BID NUMBER) MUST BE SUBMITTED IN A SEPARATE ENVELOPE. RESPONSES TO MULTIPLE BID NUMBERS SUBMITTED IN THE SAME ENVELOPE/COURIER PACKAGE, THAT ARE NOT IN SEPARATE ENVELOPES PROPERLY IDENTIFIED, WILL BE REJECTED. THE DIVISION OF PURCHASING DOES NOT ASSUME RESPONSIBILITY FOR LATE BIDS FOR ANY REASON INCLUDING THOSE DUE TO POSTAL, OR COURIER SERVICE. BID RESPONSES MUST BE IN THE DIVISION OF PURCHASING OFFICE PRIOR TO THE "RECEIVE DATE AND TIME" INDICATED ON THE BID.

3. BID RESPONSES (PAGE 1, PRICE SHEET AND ADDENDUMS (WHEN SIGNATURE IS REQUIRED)) MUST BE IN INK OR TYPED ON THIS DOCUMENT. OR EXACT FORMAT WITH SIGNATURES BEING HANDWRITTEN ORIGINALS IN INK (PERSON SIGNING BID, NOTARY, AND NOTARY EXPIRATION), OR THE BID WILL BE REJECTED. UNLESS INDICATED IN THE BID, ALL PRICE PAGES MUST BE COMPLETED AND RETURNED. IF AN ITEM IS NOT BEING BID, IDENTIFY IT AS NB (NO-BID). PAGES SHOULD BE SECURED. THE DIVISION OF PURCHASING DOES NOT ASSUME RESPONSIBILITY FOR MISSING PAGES. FAXED BID RESPONSES WILL NOT BE ACCEPTED.

4. THE UNIT PRICE ALWAYS GOVERNS REGARDLESS OF THE EXTENDED AMOUNT. A UNIT PRICE CHANGE ON A LINE MUST BE INITIALED BY THE PERSON SIGNING THE BID, OR THAT LINE WILL BE REJECTED. THIS INCLUDES A CROSS-OUT, STRIKE-OVER, INK-OVER, WHITE-OUT, ERASURE, OR ANY OTHER METHOD CHANGING THE PRICE.

5. A "NO BID" MUST BE RETURNED TO REMAIN ON A CLASS/SUBCLASS. RETURN PAGE 1 OR NOTIFICATION PAGE MARKED "NO-BID". IDENTIFY IT ON THE ENVELOPE AS A "NO-BID". FAILING TO RESPOND TO 3 ITB'S WITHIN THE SAME CLASS/SUBCLASS WILL AUTOMATICALLY PURGE THE VENDOR FROM THAT CLASS/SUBCLASS. RESPONDING WITH 6 "NO-BIDS" WITHIN THE SAME CLASS/SUBCLASS WILL AUTOMATICALLY PURGE THE VENDOR FROM THAT CLASS/SUBCLASS. A "NO-BID" RECEIVED LATE IS CONSIDERED A NO RESPONSE.

6. THE DIVISION OF PURCHASING IS NOT RESPONSIBLE FOR MISINTERPRETATION OF DATA FAXED FROM THIS OFFICE.

7. THE DIVISION OF PURCHASING REQUIRES AN ORIGINAL AND A MINIMUM OF ONE COMPLETE EXACT COPY (TO INCLUDE SIGNATURE AND NOTARY) OF THE INVITATION-TO-BID RESPONSE. THE ORIGINAL AND THE COPY SHOULD BE SUBMITTED TOGETHER AS A BID PACKAGE. FAILURE TO MARK RESPONSES AS "ORIGINAL" AND/OR "COPY" COULD RESULT IN THE ENTIRE BID RESPONSE BEING REJECTED.

8. AN IMPROPERLY SUBMITTED BID, LATE BID, OR BID THAT IS CANCELLED ON OR BEFORE THE OPENING DATE WILL BE HELD FOR 90 DAYS AND THEN DESTROYED. THE BID MUST BE RETRIEVED DURING REGULAR WORK HOURS, MONDAY - FRIDAY, EXCEPT STATE HOLIDAYS. AFTER THE BID IS DESTROYED, THE DIVISION OF PURCHASING ASSUMES NO RESPONSIBILITY FOR THE DOCUMENT.

DISQUALIFIED/CANCELLED BID

BIDS THAT ARE IMPROPERLY SUBMITTED OR RECEIVED LATE WILL BE A RESPONSE FOR RECORD, BUT WILL NOT BE RETURNED OR A NOTIFICATION MAILED.

THE FOLLOWING IS A PARTIAL LIST WHEREBY A BID RESPONSE WILL BE DISQUALIFIED:

BID NUMBER NOT ON FACE OF ENVELOPE/COURIER PACKAGE/BOX
RESPONSES TO MULTIPLE BID NUMBERS IN SAME ENVELOPE NOT PROPERLY IDENTIFIED
BID RECEIVED LATE
BID NOT SIGNED/NOT ORIGINAL SIGNATURE
BID NOT NOTARIZED/NOT ORIGINAL SIGNATURE OF NOTARY AND/OR NO NOTARY EXPIRATION
NOTARIZED OWN SIGNATURE
REQUIRED INFORMATION NOT SUBMITTED WITH BID
FAILURE TO SUBMIT THE ORIGINAL BID AND A COMPLETE EXACT COPY

CERTIFICATION PURSUANT TO ACT NO. 2006-557

ALABAMA LAW (SECTION 41-4-116,CODE OF ALABAMA 1975) PROVIDES THAT EVERY BID SUBMITTED AND CONTRACT EXECUTED SHALL CONTAIN A CERTIFICATION THAT THE VENDOR, CONTRACTOR, AND ALL OF ITS AFFILIATES THAT MAKE SALES FOR DELIVERY INTO ALABAMA OR LEASES FOR USE IN ALABAMA ARE REGISTERED, COLLECTING, AND REMITTING ALABAMA STATE AND LOCAL SALES, USE, AND/OR LEASE TAX ON ALL TAXABLE SALES AND LEASES INTO ALABAMA. BY SUBMITTING THIS BID, THE BIDDER IS HEARBY CERTIFYING THAT THEY ARE IN FULL COMPLIANCE WITH ACT NO. 2006-557, THEY ARE NOT BARRED FROM BIDDING OR ENTERING INTO A CONTRACT PURSUANT TO 41-4-116, AND ACKNOWLEDGES THAT THE AWARDING AUTHORITY MAY DECLARE THE CONTRACT VOID IF THE CERTIFICATION IS FALSE.

VENDOR NAME :

VENDOR NUMBER: -
ITB NO. : 11-X-2219994
OPEN DATE : 08/25/10 TIME: 10:00 AM
T-NUMBER : TA024
RETURN DATE: 08/24/10 TIME: 5:00 PM

INTENT TO AWARD

EFFECTIVE MAY 1, 2008, THE STATE OF ALABAMA - DIVISION OF PURCHASING WILL ISSUE AN 'INTENT TO AWARD' BEFORE A FINAL AWARD IS MADE. THE 'INTENT TO AWARD' WILL CONTINUE FOR A PERIOD OF FIVE (5) CALENDAR DAYS, AFTER WHICH A PURCHASE ORDER WILL BE PRODUCED. UPON FINAL AWARD, ALL RIGHTS TO PROTEST ARE FORFEITED. A DETAILED EXPLANATION OF THIS PROCESS MAY BE REVIEWED IN THE ALABAMA ADMINISTRATIVE CODE - CHAPTER 355-4-1(14).

ALTERNATE BID RESPONSE

UNLESS STATED ELSEWHERE IN THIS INVITATION-TO-BID (ITB) THE STATE OF ALABAMA WILL ACCEPT AND EVALUATE ALTERNATE BID SUBMITTALS ON ANY ITB'S. ALTERNATE BID RESPONSES WILL BE EVALUATED ACCORDING TO THE REQUIREMENTS AS ALL OTHER RESPONSES TO THIS ITB.

INTERNET WEBSITE LINK'S

INTERNET AND/OR WEBSITE LINKS WILL NOT BE ACCEPTED IN BID RESPONSES AS A MEANS TO SUPPLY ANY REQUIREMENTS STATED IN THIS ITB (INVITATION-TO-BID).

PRODUCT DELIVERY, RECEIVING AND ACCEPTANCE

IN ACCORDANCE WITH THE UNIVERSAL COMMERCE CODE (CODE OF ALABAMA, TITLE 7), AFTER DELIVERY, THE STATE OF ALABAMA HAS THE RIGHT TO INSPECT ALL PRODUCTS BEFORE ACCEPTING. THE STATE WILL INSPECT PRODUCTS IN A REASONABLE TIMEFRAME. SIGNATURE ON A DELIVERY DOCUMENT DOES NOT CONSTITUTE ACCEPTANCE BY THE STATE. THE STATE WILL ACCEPT PRODUCTS ONLY AFTER SATISFACTORY INSPECTION.

SALES TAX EXEMPTION

PURSUANT TO THE CODE OF ALABAMA, 1975, TITLE 40-23-4 (A) (11), THE STATE OF ALABAMA IS EXEMPT FROM PAYING SALES TAX. AN EXEMPTION LETTER WILL BE FURNISHED UPON REQUEST.

INVOICES

INQUIRIES CONCERNING PAYMENT AFTER INVOICES HAVE BEEN SUBMITTED ARE TO BE DIRECTED TO THE RECEIVING AGENCY, NOT THE DIVISION OF PURCHASING

BID RESPONSES AND BID RESULTS

UNEVALUATED BID RESPONSES (NOT BID RESULTS) ARE AVAILABLE ON OUR WEB SITE AT WWW.PURCHASING.ALABAMA.GOV. BID RESULTS WILL BE MADE AVAILABLE FOR REVIEW IN THE DIVISION OF PURCHASING OFFICE, BUT ONLY AFTER THE BID HAS BEEN AWARDED. WE DO NOT FAX OR MAIL COPIES OF BID RESULTS. IF A VENDOR WISHES TO REVIEW BID RESULTS IN OUR OFFICE, THEY SHOULD FAX THEIR REQUEST TO REVIEW THE BID TWO DAYS IN ADVANCE TO THE "BID REVIEW CLERK" AT (334) 242-4419. BE SURE TO REFERENCE THE BID NUMBER.

FOREIGN CORPORATION - CERTIFICATE OF AUTHORITY

ALABAMA LAW PROVIDES THAT A FOREIGN CORPORATION (AN OUT-OF-STATE COMPANY/FIRM) MAY NOT TRANSACT BUSINESS IN THE STATE OF ALABAMA UNTIL IT OBTAINS A CERTIFICATE OF AUTHORITY FROM THE SECRETARY OF STATE. SECTION 10-2B-15.01, CODE OF ALABAMA 1975. TO OBTAIN FORMS FOR A CERTIFICATE OF AUTHORITY, CONTACT THE SECRETARY OF STATE, CORPORATIONS DIVISION, (334) 242-5324. THE CERTIFICATE OF AUTHORITY DOES NOT KEEP THE VENDOR FROM SUBMITTING A BID.

BID IDENTIFICATION

REFERENCE PAGE 2, ITEM 2. DUE TO THE POSTAL SERVICE PUTTING BAR CODE LABELS ON ENVELOPES, IT CONCEALS THE BID NUMBER AND DATE IF THE VENDOR HAS WRITTEN THEM OTHER THAN THE LOWER LEFT CORNER, THEREFORE THE BID WOULD BE REJECTED FOR NOT BEING PROPERLY IDENTIFIED.

AWARD:
AWARD WILL BE MADE "ALL OR NONE" TO THE LOWEST RESPONSIBLE BIDDER MEETING ALL SPECIFICATIONS.

PERISHABLE PRODUCT SHIPMENTS:
ALL PERISHABLE PRODUCTS ARE TO BE SHIPPED PREPAID BY GUARANTEED OVER-NIGHT DELIVERY SERVICE WITH VENDOR ASSUMING ALL FREIGHT CHARGES.

FREIGHT:
BID IS F.O.B. DESTINATION. ANY FREIGHT CHARGES MUST BE INCLUDED IN THE BID PRICES.

CONTRACT PERIOD:
ESTABLISH A 12 MONTH CONTRACT WITH AN OPTION TO EXTEND FOR A SECOND, THIRD, FOURTH, AND FIFTH 12 MONTH PERIOD WITH THE SAME PRICING, TERMS AND CONDITIONS. THE SECOND, THIRD, FOURTH, OR FIFTH 12 MONTH PERIOD, IF AGREED BY BOTH PARTIES, WOULD BEGIN THE DAY AFTER THE FIRST, SECOND, THIRD, OR FOURTH 12 MONTH PERIOD EXPIRES. ANY SUCCESSIVE EXTENSION MUST HAVE WRITTEN APPROVAL OF BOTH THE STATE AND VENDOR NO LATER THAN 30 DAYS PRIOR TO EXPIRATION OF THE PREVIOUS 12 MONTH PERIOD.

NON-APPROPRIATION OF FUNDS:
CONTINUATION OF ANY AGREEMENT BETWEEN THE STATE AND A BIDDER BEYOND A FISCAL YEAR IS CONTINGENT UPON CONTINUED LEGISLATIVE APPROPRIATION OF FUNDS FOR THE PURPOSE OF THIS BID AND ANY RESULTING AGREEMENT. NON-AVAILABILITY OF FUNDS AT ANY TIME SHALL CAUSE ANY AGREEMENT TO BECOME VOID AND UNENFORCEABLE AND NO LIQUIDATED DAMAGES SHALL ACCRUE TO THE STATE AS A RESULT. THE STATE WILL NOT INCUR LIABILITY BEYOND THE PAYMENT OF ACCRUED AGREEMENT PAYMENT.

PRORATION:
ANY PROVISION OF A CONTRACT RESULTING FROM THIS BID TO THE CONTRARY NOTWITHSTANDING, IN THE EVENT OF FAILURE OF THE STATE TO MAKE PAYMENT HEREUNDER AS A RESULT OF PARTIAL UNAVAILABILITY, AT THE TIME SUCH PAYMENT IS DUE, OF SUCH SUFFICIENT REVENUES OF THE STATE TO MAKE SUCH PAYMENT (PRORATION OF APPROPRIATED FUNDS FOR THE STATE HAVING BEEN DECLARED BY THE GOVERNOR PURSUANT TO SECTION 41-4-90 OF THE CODE OF ALABAMA 1975), THE CONTRACTOR SHALL HAVE THE OPTION, IN ADDITION TO THE OTHER REMEDIES OF THE CONTRACT, OF RENEGOTIATING THE CONTRACT (EXTENDING OR CHANGING PAYMENT TERMS OR AMOUNTS) OR TERMINATING THE CONTRACT.

BID UNITS/PACKAGING:
BIDS ARE REQUESTED IN UNITS AS SPECIFIED, OR STANDARD PACK, AS SHOWN IN THE ITEM LISTING. ALTERNATE PACKAGING WILL BE GIVEN CONSIDERATION, BUT IT MUST BE EQUIVALENT IN SIZE TO THAT SPECIFIED/ACCEPTABLE FOR ITS INTENDED USE. IF BIDDING A DIFFERENT PACKAGING, INDICATE IT AT THE COMMODITY DESCRIPTION.

DESCRIPTIVE LITERATURE:
THE BRANDS AND MODEL NUMBERS REFERENCED PROVIDE A LEVEL OF QUALITY, AND UNLESS OTHERWISE SPECIFIED, ARE NOT RESTRICTIVE. VENDORS BIDDING ALTERNATE ITEMS MUST PROVIDE COMPLETE DESCRIPTIVE/TECHNICAL LITERATURE FOR CONSIDERATION AND EVALUATION WITH THEIR BID, AND WITH THE BID COPY PER ITEM NUMBER 7 ON PAGE 2. REFERENCE TO LITERATURE WITH A PREVIOUS BID WILL NOT SATISFY THIS REQUIREMENT. FAILURE TO PROVIDE THE REQUIRED LITERATURE WILL RESULT IN THE REJECTION OF THE BID. PHYSICAL INSPECTION AND OPERATIONAL EVALUATION MAY ALSO BE REQUIRED WITHOUT COST OR OBLIGATION TO THE STATE OF ALABAMA.

ITEM DESCRIPTION AND UNIT OF MEASURE:
IF THE ITEM DESCRIPTION/UNIT OF MEASURE DIFFER FROM THOSE LISTED, IT MUST BE CHANGED AT THE ITEM LEVEL, OTHERWISE THE STATED DESCRIPTION AND UNIT OF MEASURE WILL APPLY.

QUANTITY:

THE EXACT QUANTITY OF PURCHASES FOR EACH ITEM LISTED IS NOT KNOWN. QUANTITY SHOWN REFLECTS ESTIMATED ANNUAL USAGE ONLY. THE DIVISION OF PURCHASING DOES NOT GUARANTEE THAT THE STATE WILL BUY ANY AMOUNT. ORDERS WILL BE PLACED BY AGENCIES AS NEEDED AND WILL GIVE COMPLETE SHIPPING INSTRUCTIONS.

BIDDABLE SITUATION:
BIDS MAY BE SOLICITED FOR ANY PRODUCT INCLUDED IN THIS CONTRACT WHERE AN IMMEDIATE/EMERGENCY NEED EXISTS, INCLUDING LARGE QUANTITIES. THE DECISION OF THE PURCHASING DIRECTOR AS TO WHAT CONSTITUTES A BIDDABLE SITUATION SHALL BE FINAL AND SHALL NOT BE CONSTRUED AS A BREACH OF CONTRACT.

PRICE SHEET

INVITATION TO BID

VENDOR NAME:

VENDOR NO : -
ITB NO. : 11-X-2219994
OPEN DATE : 08/25/10 TIME: 10:00 AM
T-NUMBER : TA024
RETURN DATE: 08/24/10 TIME: 5:00 PM

LINE NO	DESCRIPTION / BRAND NAME	RECYCLE /ENERGY	QUANTITY	UNIT	AMOUNT	STK NUMBER	UNIT PRICE	EXTENDED PRICE	N/A
	UNLESS SPECIFIED OTHERWISE BELOW: SHIP TO: R1 / STATEWIDE								
00001	COMMODITY CODE: 193-36-065694 CHLAMYDIA TEST KIT FOR DETECTION AND CONFIRMATION PER ATTACHED SPECIFICATION.	___	1	KIT	_____	_____	_____	_____	_____

PAGE TOTAL _____

BID TOTAL _____

BID SPECIFICATIONS

Chlamydia trachomatis/ Neisseria gonorrhoeae Nucleic Amplification Assay

Trichomonas vaginalis Nucleic Amplification Assay

A. *Chlamydia trachomatis/ Neisseria gonorrhoeae* Nucleic Amplification Assay

1. The assay must utilize nucleic amplification technology (NAAT) for the detection of *Chlamydia trachomatis* and *Neisseria gonorrheae* (CTGC) in endocervical swabs, male urethral specimens, male and female urines, and vaginal swabs either patient or physician collected.
2. The assay must be approved by the Bureau of Biologics of the Food and Drug Administration (FDA) for *in vitro* diagnostic use with either symptomatic or non-symptomatic patients using eithern endocervical, male urethral, male or female urine specimens and vaginal specimens.
3. Manufacturer must be able to claim equivalent test performance across all FDA approved specimen collection types.
4. The assay must process all specimen types identically and simultaneously with no specimen segregation or analyst manipulation such as cap removal, swab expression, swab removal or centrifugation.
5. The assay's performance should not be affected by either naturally occurring components in patient samples such as blood, mucous, or bilirubin, nor man-made components such as vitamins or gynecological products.
6. The assay should not cross-react with organisms other than CTGC.
7. The assay must have FDA acknowledged sensitivity (versus patient infected status) of at least 94% (*Chlamydia trachomatis)* and 91% (*Neisseria gonorrhoeae*) with a specificity (versus patient infected status) of at least 97% for both analytes.
8. The assay must be automated such that five hundred (500) combined CTGC samples (patient specimens) can be tested using one analyst in an 8.0 hour period.
9. The Vendor will provide at no additional cost all specimens, specimen collection kits, reagents, test kits, etc., required to verify the assay system to satisfy the current CLIA-88 requirements for verification. Anticipated volume for method verification is 100 tests. Successful completion required for final acceptance.

ESTIMATED USAGE: Montgomery 85,000; Mobile 42,000

B. *Trichomonas vaginalis* Nucleic Amplification Assay

1. The assay must utilize nucleic amplification technology (NAAT) for the detection of *Trichomonas vaginalis* (TV) in endocervical swabs, male urethral specimens, male and female urines, and vaginal swabs either patient or physician collected.
2. Manufacturer must be able to claim equivalent test performance across all specimen collection types.
3. The assay must process all specimen types identically and simultaneously with no specimen segregation or analyst manipulation such as cap removal, swab expression, swab removal or centrifugation.
4. The assay's performance should not be affected by either naturally occurring components in patient samples such as blood, mucous, or bilirubin, nor man-made components such as vitamins or gynecological products.
5. The assay must be automated such that five hundred (500) combined CTGC samples (patient specimens) can be tested using one analyst in an 8.0 hour period.
6. The Vendor will provide at no additional cost all specimens, specimen collection kits, reagents, test kits, etc., required to validate/ verify the assay system to satisfy the current CLIA-88 requirements. Anticipated volume for method verification is 100 tests. Successful completion of validation/ verification required for final acceptance.

ESTIMATED USAGE: To be determined when and if test is approved by the administration.

Reagents

1. All reagents and equipment must be provided on a reagent rental basis, i.e., reagent purchase/ equipment provided basis.
2. Reagents must be supplied in a form requiring minimal preparation, and in a configuration and package size compatible with the projected user volume.
3. Delivery of reagents must be guaranteed within ten (10) working days after receipt of an order.

4. Test kits must have a minimum of two (2) months of the expiration date remaining at the time they are received in the laboratory.

Collection Kits

1. Specimen collection kits must be offered by the Vendor for use with their CTGC and TV NAAT assays. The Vendor will work with the laboratory and field personnel to ensure that an acceptable plan is in place to replace existing specimen collection kits with new specimen collection kits if necessary.
2. Specimen collection kits should not require refrigerated storage.
3. Specimen collection kits must utilize a penetrable cap for use with automated pipetting instrumentation.
4. Collected specimens must be acceptable for testing at least seven (7) days post collection when shipped or stored under ambient conditions.

Equipment/Instrumentation

1. Equipment/Instrumentation is to be provided for use under a reagent purchase plan.
2. The Vendor is responsible for providing no cost preventive maintenance service (PM) per the manufacturer's recommendations and non-routine repair of instrumentation or equipment.
3. Equipment/Instrumentation design requirements should not exceed the area established for the current testing in the laboratory.
4. Equipment/Instrumentation must be compatible with existing electrical supply and environmental conditions; the Vendor is responsible for any required modifications. All work must meet or exceed applicable local building and safety codes; inspection certificates required for final acceptance.
5. The Vendor is responsible for the delivery, unpacking, installation, and set-up of any provided equipment or instrumentation. At the end of the contract period, the Vendor is responsible for the disassembly, packing, removal and shipping of provided equipment or instrumentation.

6. Instrumentation minimum requirements:
    - Positive patient specimen identification throughout testing via onboard barcode tracking.
    - Automated reagent and specimen pipetting capabilities.
    - Liquid level detection for both reagents and patient samples
    - Reagent lot number and expiration date tracking
    - Onboard destruction of post test amplicons
    - Liquid and solid waste monitoring system
    - Must be capable of bi-directional interface to the current laboratory information system (LIS). See general requirements below.

LIS

1. The Vendor must provide, at no cost to the BCL, a validated, robust, and functioning bi-directional instrument interface to the BCL LIS within 30 days of installation.
2. Must have a safe memory for programs with a file protection scheme.
3. Software must be menu-driven with a full numeric keypad.
4. The user must be able to protect programs against unauthorized modifications.
5. Must be capable of running Symantec Antivirus 7.5 and above without affecting performance.
6. Must have a Windows XP operating system or equivalent.

Other Requirements

1. In addition to the FDA approved combination assay for CTGC, the Vendor should offer FDA approved individual discriminatory assays which target alternative unique genomic regions on the same instrumentation platform.
2. If test volume increases by 30% or more during the contract period, the Vendor must provide, at no cost to the BCL, additional or updated instrumentation and upgraded data management systems to accommodate the work load increase.
3. The Vendor must comply with applicable HIPPA regulations to maintain the confidentiality of patient demographics and test data. "HIPPA Requirements" below.

Technical Support/Training

1. Vendor technical assistance via telephone must be available within 30 minutes during normal business hours and within 4 hours during non-business hours for reported problems.
2. On-site technical backup must be guaranteed within 24 hours of any reported assay failure for equipment for which in-house troubleshooting was unsuccessful.
3. The Vendor must provide technical training at the Vendor's headquarters for two (2) technologists per instrument provided. Training should be in depth and intensive to include: assay performance, troubleshooting, preventive maintenance, and quality control.
4. The Vendor will also provide on-site technical training to pertinent personnel regarding assay performance, troubleshooting, preventative maintenance, and quality control.

BID ALL OR NONE

HIPPA Requirements

Federal Requirement. This Clause is necessitated by the application of the Health Insurance Portability and Accountability Act, being 42 U.S.C. §§ 1320d-1329d-8 as amended by § 262 of P.L.104-191, 110 Stat. 2020-2031 and § 264 of P.L.104-191 (42 U.S.C. § 1320d-2 as amended) and regulations promulgated thereunder. References in this clause are to the Code of Federal Regulations, hereinafter "CFR."

1. Definitions Terms used, but not otherwise defined, in this Clause shall have the same meaning as in the Department of Health and Human Services' Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule") and Security of Electronic Protected Health Information ("Security Rule"), 45 CFR Parts 160 through 164.

a. "Contractor" The Contractor herein. The Contractor is within the definition of a "Business Associate" under the Privacy Rule. Shall refer to Contractor and/or any of its employees.

b. "Department" The Department herein. Department is within the definition of a "Covered Entity" under the Privacy Rule.

c. "Improper disclosure" means actual disclosure (including mailing or e-mailing protected information to the wrong physical or e-mail addresses and posting of protected information to unauthorized websites), or loss of control of the protected information (including loss of records in transit, physical burglary, electronic record intrusion), and other events indicating that the protected information actually was disclosed to unauthorized parties or there is a reasonable likelihood that it may have been disclosed to unauthorized parties.

d. "Individual" shall have the same meaning as the term "individual" in 45 CFR. § 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR § 164.502(g).

e. "Privacy Rule" Privacy Rule shall mean the Standards for Privacy of Individually Identifiable Health Information found at 45 CFR. Part 160 and Part 164, Subparts A and E.

f. "Proper notification" to ADPH means sending an electronic message to Sharon P. Massingale, Ph. D. and Marian M. Woodman at the following email addresses, sharon.massingale@adph.state.al.us and marian.woodman@adph.state.al.us and a written letter to Sharon P. Massingale, Ph. D. and Marian M. Woodman at the following, Bureau of Clinical Laboratories, P.O. Box 244018, Montgomery, AL 36124-4018, within 48 hours of the improper disclosure event. In the case that Contractor has reason to believe that receipt by neither of these parties was actually accomplished Contractor will notify John R. Wible at the following email address jwible@adph.state.al.us, as soon as possible after recognizing the failure of the original notification.

g. "Protected Health Information" shall mean individually identifiable health information and Electronic Protected Health Information as found in the Security Rule, 45 CFR ' 160.103, except for that information in (a) education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. ' 1232g, (b) records described at 20 U.S.C. ' 1232g (a) (4) (B) (iv), and (3) employment records held by Department in its role as employer, or as the term may otherwise be defined in 45 CFR ' 164.501.

h. "Protected individuals" means ADPH's patient , or clients, or employees, former employees, their spouses, dependents, or other individuals whose protected information was provided by or on ADPH's behalf to Contractor or its subcontractors in connection with Contractor's services under this Contract.

i. "Protected Information" means individuals' Social Security Numbers; credit, banking, and other financial information; and protected health information, or information from an employee or former employers personnel or health information file.

j. "Required By Law" shall mean any mandate contained in law that compels Department to make a use or disclosure of Protected Health Information and that is enforceable in a court of

law, including, but not limited to, court orders and court-ordered warrants, subpoenas or summons, a civil or an authorized investigative demand, Medicare conditions of participation (if applicable), statutes or regulations requiring the production of information, or as the term may otherwise be defined in 45 CFR ' 164.501.

k. "Secretary" The Secretary of the United States Department of Health and Human Services or his designee.

l. "Designated Record Set" Means the medical and billing records maintained by or for Department about a Department patient, or any other group of records used by or for Department to make decisions about the patient.

m. "Security Rule" shall mean the Security Standards for the Protection of Electronic Health Information at 45 CFR Part 160 and part 164, Subparts A and C.

2. Obligations and Activities of Contractor

a. Use and Disclosure of Protected Health Information. Contractor agrees not to use or further disclose Protected Health Information other than as permitted or required by the Contract or as Required By Law.

b. Safeguards. Contractor shall use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Contract.

c. Mitigation of Damages Contractor shall mitigate, to the extent practicable, any harmful effect that is known to of a use or Contractor disclosure of Protected Health Information by Contractor in violation of the requirements of this Contract.

d. Reporting Violations Contractor shall within (5) days of becoming aware of a use or disclosure or security incident in violation of this Contract, report the use or disclosure to. Department

e. Agents and Contractors Contractor agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by Contractor on behalf of Department agrees to the same restrictions and conditions that apply through this Contract to Contractor with respect to such information.

f. Access to Protected Health Information If Contractor maintains a PHI Designated Record Set, Contractor shall, within five (5) days of a request by Department for access to a patient's PHI make available to Department the requested PHI that Contractor maintains in Designated Record Sets, in accordance with 45 CFR 164.524.

g. Amendment of Protected Health Information If Contractor maintains a PHI in Designated Record Set, Contractor shall, within 10 days of receiving a request from Department for the amendment of a patient's PHI, incorporated the amendment into the information that

Contractor maintains in a Designated Record Set in order to meet the requirements under 45 CFR 164.526.

h. Books and Records If Contractor maintains a Designated Record Set, Contractor agrees to make its facilities, internal practices, books, accounts, other sources of information and records relating to the use and disclosure of Protected Health Information received from, or created or received by Contractor on behalf of Department available to the Department, or at the request of the Department to the Secretary, during normal business hours or as otherwise directed by the Secretary for purposes of determining the parties' compliance with the applicable standards, implementation specifications and other requirements of the Privacy Rule.

i. Accounting of Disclosures Contractor shall within ten (10) days of receiving notice from Department that it has received a request from a patient for an accounting of disclosures of PHI, provide to Department or, if so directed, to the patient or the patient's personal representative, information relating to disclosures of the PHI made, including (i) the date of the disclosure, (ii) the name of the entity or person who received the information, (iii) a brief description of the information disclosed, and (iv) a brief statement of the purpose of the disclosure which includes an explanation of the basis for the disclosure, pursuant to 45 CFR 164.528.

j. Implementing Safeguards for Electronic PHI (1) Contractor shall implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of the electronic protected health information that it creates, receives, maintains, or transmits on behalf of Department as required by the Security Rule. (2) Contractor agrees to ensure that any agent, including a, Contractor to whom it provides this information agrees to implement reasonable and appropriate safeguards to protect the electronic protected health information.

k. Confidentiality In addition to any other protections provided for in this Contract, Contractor agrees to properly notify ADPH within 48 hours of learning of the event of any improper disclosure or suspected improper disclosure of protected information that Contractor or Contractor's subcontractors receive, store, create, or transmit related to ADPH's protected individuals.

Contractor further agrees to use its best efforts to determine how the improper disclosure of the protected information occurred and to take reasonable remedial action to prevent a reoccurrence. In addition, Contractor will remediate improper disclosures made by Contractor or its subcontractors by covering the expenses related to timely notifying the affected protected individuals about the disclosure; and in the event of actual disclosure to cover the expenses related to procuring commercial monitoring of the affected protected individuals' security for a period of one year, unless ADPH consents that such monitoring is unnecessary in the particular circumstances surrounding the event. ADPH will not unreasonably withhold such consent.

3. Permitted Uses and Disclosures by Contractor

a. Permitted Uses and Disclosures by Contractor Except as otherwise limited in this Contract, Contractor may use or disclose Protected Health Information on behalf of Department,

or to perform functions, activities, or provide services to, Department or patients or clients of Department for the purposes of providing health care to patients and clients in accordance with Department's Confidentiality Policy, if such use or disclosure of Protected Health Information would not otherwise violate the Privacy Rule if such disclosure is made by Department.

b. Uses for Management and Administration Purposes Except as otherwise limited in this Contract, Contractor may use Protected Health Information for the proper management and administration of the Contractor or to carry out the legal responsibilities of the Contractor.

c. Disclosures for Management and Administration Purposes Except as otherwise limited in this Contract, Contractor may disclose Protected Health Information for the proper management and administration of the Contractor, provided that disclosures are required by law, or Contractor obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and will be used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies the Contractor of any instances of which it is aware in which the confidentiality of the information has been breached.

d. Data Aggregation Services. Except as otherwise limited in this Contract, Contractor may use Protected Health Information to provide Data Aggregation services to Department as permitted by 42 CFR § 164.504(e)(2)(i)(B).

4. Obligations of Department

a. Notification of Elected Limitations Department shall provide Contractor with Department's Privacy Notice which Department produces in accordance with 45 CFR § 164.520, as well as any changes to such notice.

b. Notification of Changes in Authorization Department shall provide Contractor with any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, if such changes affect Contractor's permitted or required uses and disclosures.

c. Notification of Restrictions Department shall notify Contractor of any restriction to the use or disclosure of Protected Health Information that Department has agreed to in accordance with 45 CFR § 164.522.

5. Permissible Requests by Department Department shall not request Contractor to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by Department except that if the Contractor will use or disclose protected health information for data aggregation or management and administrative activities of Contractor, such information may be requested.

6. Return of Information and Survival of the terms of this Clause The provisions of this paragraph shall survive the termination of this Contract and may constitute a continuing duty in perpetuity

a. Except as otherwise provided, upon termination of this Contract for any reason, Contractor shall delete, return or destroy all Protected Health Information maintained in a designated record set received from Department, or created or received by Contractor on behalf of Department or as a result of this Contract. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Contractor. Where such information is deleted or destroyed, Contractor shall provide Department with an assurance of the deletion or destruction of such.

b. Except in accordance with normal business practices, Contractor shall retain no copies of the Protected Health Information.

c. In the event that Contractor determines that returning or destroying the Protected Health Information is infeasible, Contractor shall provide to Department notification of the conditions that make return or destruction infeasible. Upon mutual Contract of the Parties that return or destruction of Protected Health Information is infeasible, Contractor shall extend the protections of this Contract to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Contractor maintains such Protected Health Information.

7. Administrative Provisions

a. A reference in this Contract to a section of the Privacy Rule shall mean that section as it is most recently amended.

b. The parties hereto agree to take necessary action as is necessary to amend this Contract from time to time to maintain compliance with the Privacy Rule.

c. Interpretation. Any ambiguity in this Contract regarding the application of the Privacy Rule shall be resolved in favor of a meaning which permits the parties hereto to comply with the Privacy Rule.